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A Pharmaceutical Care Program to Improve Adherence to Statin Therapy: A Randomized Controlled Trial

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BACKGROUND: Despite the well-known beneficial effects of statins, many patients do not adhere to chronic medication regimens.

OBJECTIVE: To implement and assess the effectiveness of a community pharmacy–based pharmaceutical care program developed to improve patients' adherence to statin therapy.

METHODS: An open-label, prospective, randomized controlled trial was conducted at 26 community pharmacies in the Netherlands. New users of statins who were aged 18 years or older were randomly assigned to receive either usual care or a pharmacist intervention. The intervention consisted of 5 individual counseling sessions by a pharmacist during a 1-year period. During these sessions, patients received structured education about the importance of medication adherence, lipid levels were measured, and the association between adherence and lipid levels was discussed. Adherence to statin therapy was assessed as discontinuation rates 6 and 12 months after statin initiation, and as the medication possession ratio (MPR), and compared between the pharmaceutical care and usual care groups.

RESULTS: A total of 899 subjects (439 in the pharmaceutical care group and 460 in the usual care group) were evaluable for effectiveness analysis. The pharmaceutical care program resulted in a significantly lower rate of discontinuation within 6 months after initiating therapy versus usual care (HR 0.66, 95% CI 0.46 to 0.96). No significant difference between groups was found in discontinuation at 12 months (HR 0.84, 95% CI 0.65 to 1.10). Median MPR was very high (>99%) in both groups and did not differ between groups.

CONCLUSIONS: These results demonstrate the feasibility and effectiveness of a community pharmacy–based pharmaceutical care program to improve medication adherence in new users of statins. Frequent counseling sessions (every 3 months) are necessary to maintain the positive effects on discontinuation. Although improvements are modest, the program can be applied easily to a larger population and have a large impact, as the interventions are relatively inexpensive and easy to implement in clinical practice.

KEY WORDS: adherence, cardiovascular drugs, lipids, pharmaceutical care.

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Despite the well-known beneficial effects of statins, adherence to statin treatment is poor in daily medical practice. One-year persistence with statins has been estimated to be about 60% in patients with previous cardiovascular events[1-3]; in primary prevention, discontinuation rates are likely to be even higher.[3,4] Poor adherence is a major barrier to successful treatment. Therefore, potential benefits of statins as established in randomized controlled trials may not be accomplished in clinical practice. Both the World Health Organization and the European Council have advocated for a multidisciplinary approach in addressing nonadherence. In this approach, the community pharmacist has an important role to play in ensuring that drug therapy is appropriate and the patient has an optimal chance of success with therapy.[5,6] Community-based pharmacists are the most easily accessible health-care providers, have extensive knowledge about drug therapy and disease management, and can provide information and education to the patient and monitor adherence.

Several randomized controlled trials have been conducted in which pharma-

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ceutical interventions to enhance medication adherence have been implemented.[7-17] Evaluated interventions range from giving patients more information and education on the goals and benefits of drug therapy to the simplification of the drug regimen and intensification of patient care by telephone reminders, home visits, and follow-up interviews. Most randomized controlled trials showed beneficial effects on adherence,[10,15,17] lipid levels,[7,8,13,14,16] or both.[9] Moreover, overall health-care expenditures in the intervention and control groups seem to be similar, despite increased visits to the pharmacist and laboratory costs.[8]

It has been shown that the most critical need for adherence interventions is during the first few months of therapy, as adherence levels drop shortly after initiation of statin treatment.[18] Hence, persons who have been newly prescribed medications comprise an interesting subgroup when pharmaceutical care programs are implemented. Most studies aimed at improving adherence among users of statins were hospital pharmacy–based,[7-10,14,16] sometimes with complex interventions[10,14,17] and mostly not focusing solely on patients initiating statin treatment.[7,8,10-14,16] We therefore developed a large multicenter community pharmacy–based pharmaceutical care program for new statin users. This program was aimed at improving adherence to statin therapy by giving patients education and feedback on achieved lipid levels. These interventions are easy to implement in community pharmacies, are relatively inexpensive, and have been shown to be effective in clinical trials with various patient populations.[13,14] The purpose of our study was to examine the feasibility and effectiveness of this program.

Methods

STUDY POPULATION

Our study, the STIPT (STatin Intervention research ProjecT), was a community pharmacy–based, multicenter, open-label, randomized controlled trial to improve medication adherence in new users of statins. Patients were recruited from 26 community pharmacies (both independent and chain stores) in the Netherlands and were eligible for inclusion if they were new users of statins, were aged 18 years or older, and were capable of visiting the pharmacy. New users were defined as those who had not filled a prescription for statins in the preceding 6 months, verified by the pharmacist through a patient record check. Virtually all Dutch inhabitants are registered with a single community pharmacy, independent of prescriber; consequently, pharmacy records are nearly complete with regard to prescription drugs.[19] The study was approved by the Medical Committee of Ethics of the University Medical Centre Utrecht and all patients signed informed consent forms prior to the study. Study enrollment started in September 2004 and was completed in March 2006.

STUDY DESIGN

Once the informed consent form was received, each participant was randomly assigned to either the intervention or control group by a procedure that was built into the computer system and used a set of random numbers in a 1:1 ratio. Patients in the intervention (pharmaceutical care) group were invited to visit the pharmacy for 5 individual counseling visits, each lasting 10-15 minutes. Counseling visits were scheduled at first prescription, at second prescription (after 15 days), and at subsequent refill dates at 3, 6, and 12 months after the start of statin therapy. In the Netherlands, the first prescription for statins is limited to 15 days[20] and subsequent prescriptions are generally dispensed in 3-month supplies. Because it has been shown that patients are most likely to discontinue statins in the first months after therapy initiation,[18] counseling sessions were scheduled more frequently during the first months of treatment. Counseling at time of first prescription comprised structured education on indication, effects, and adverse effects of statin therapy; dosage; importance of medication adherence; and intended duration of treatment. Additionally, a drug information letter that summarized the verbal information was given to each patient. At the time of the second prescription, patients were asked about their experience with statin therapy, potential drug-related problems, and difficulties in adhering to the dosing regimen. At 3, 6, and 12 months, total cholesterol, high-density lipoprotein cholesterol, and triglyceride levels were measured from fasting fingerstick whole blood samples using Cholestech LDX Analyzers (Cholestech Corp., Hayward, CA) and low-density lipoprotein cholesterol (LDL-C) was estimated by the Friedewald formula.[21] Measured lipid levels and treatment goals were recorded on a wallet card that was kept by all patients to monitor their progress in lowering lipid levels. In addition, medication adherence was assessed via unused pill counts, and the association between adherence and lipid levels was discussed to encourage patients to adhere to the prescribed dosing regimen.

Patients in the control group were provided usual care, consisting of verbal and written drug information according to the standard protocol in the pharmacies. Patients in the usual care group did not receive lipid measurements or counseling sessions.

In both the pharmaceutical care and usual care groups, patients were asked to fill out a questionnaire at baseline and after 6 and 12 months. The baseline questionnaire included items on sociodemographics, family history of cardiovascular disease (CVD), comorbidities, self-perceived health, lifestyle factors (smoking habits, alcohol consumption, dietary habits), and the application of other lipid-lowering strategies (eg, eating healthier or becoming more physically active). Questionnaires at 6 and 12 months contained questions about changes in self-perceived health and lifestyle modifications to lower lipid levels.

All questions about the study or treatment from patients in both treatment arms were answered as forthrightly as possible. Participants and those administering the interventions were not blinded to the treatment assignment. Conversely, those assessing differences in outcomes between the pharmaceutical care and usual care groups remained blinded throughout the study.

OUTCOME DEFINITION

Electronic pharmacy dispensing records of all patients were collected at the end of follow-up. Adherence to statins was evaluated in terms of discontinuation of treatment and the medication possession ratio (MPR).[22] The primary endpoint of this study was discontinuation of treatment assessed 1 year after the start of statin therapy. Secondary endpoints were discontinuation rates 6 months after statin initiation, the MPR, and the relation between MPR and total cholesterol and LDL-C levels. Patients were considered to have discontinued therapy if they failed to refill their statin agents within 90 days or 1 time the theoretical duration of the prescription, whichever was the lowest number of days.[23] Time to discontinuation was defined as the number of days between the start of statin therapy and the discontinuation day. When a patient refilled a prescription for the same type of statin before the theoretical end date of the previous prescription, we assumed that the new prescription began after the end date of the previous one.[24] Patients who switched from one type of statin to another were considered to be continuous users. Patients were censored at the end of the study period or when they changed to a pharmacy not participating in the study or died before the end of follow-up. The patient's MPR was assessed from the pharmacy dispensing records at the end of the study or, for patients who stopped statin therapy earlier, at the time of discontinuation. The MPR was calculated as the ratio of the sum of the days' supply of all statin medication dispensed divided by the length of therapy. A patient with an MPR of 0.9 or more was defined as being adherent to the prescribed dosing regimen. Medication adherence assessed by pill counts during the counseling sessions was not regarded as an outcome of this study but was used solely to instantly address an individual's adherence at the counseling session.

STATISTICAL ANALYSIS

Necessary sample size was estimated with the assumption of a 1-year discontinuation rate of 33% in the control group, as suggested by a previous study in a comparable patient population,[25] and of 24% in the pharmaceutical care group. The pharmaceutical care discontinuation rate was chosen conservatively based on previous effects of community pharmacy–based programs.[15,17] With an 80% power of detecting a significant difference ($p = 0.05$, 2-sided) between the 2 groups and an expected loss to follow-up of 20%, a sample size of 493 patients in each group (986 total) was required.

Patient characteristics were compared between the pharmaceutical care and usual care groups using an independent sample Student's *t*-test or χ^2 test as appropriate. Discontinuation was estimated by using Kaplan-Meier analysis and was compared between the groups with a log-rank test. Univariate Cox proportional hazard models were used to compare further the probability of discontinuation between the groups. In addition, Cox proportional hazard models were used to estimate the probability of discontinuation at 12 months in various exploratory subgroups that were defined by factors potentially associated with discontinuation. Those factors were age, sex, level of education, comorbidities (hypertension, diabetes, history of CVD), familial hypercholesterolemia, the application of other lipid-lowering strategies, and the number of medications used (at Anatomical Therapeutic Chemical [ATC] classification level 3).[26] A treatment-by-subgroup interaction term was added to the model to test whether different subgroups had different risks. The MPR between the 2 study groups was analyzed using the nonparametric Mann-Whitney *U* test and the percentage of subjects having a high (≥90%) or low (<90%) MPR was compared using the χ^2 test. The number of subjects switching to a statin with a different equipotency score (measure for the potency of a statin to lower total cholesterol according to type and dose)[27] was computed and compared between the pharmaceutical care and usual care groups with the Mann-Whitney *U* test.

Lipid levels were measured only in the intervention group as part of the pharmaceutical care program; therefore, the effect of differences in MPR on lipid levels could be estimated only in these subjects. Patients were considered to have met lipid treatment goals if they achieved fasting total cholesterol levels of <190 mg/dL and LDL-C levels of <115 mg/dL.[28,29] The percentage of subjects reaching lipid goals among patients with a high (≥90%) or low (<90%) MPR was compared using the χ^2 test. Spearman correlation was used to determine the relationship between the MPR and lipid levels.

The results were considered statistically significant at a 2-sided probability level of $p < 0.05$. All statistical analyses were performed according to the intention-to-treat principle using SAS version 9.1.3 (SAS Institute, Cary, NC).

Results

PATIENT ENROLLMENT AND BASELINE CHARACTERISTICS

A total of 1016 subjects were enrolled in the trial, 513 (50%) of whom were randomized to the pharmaceutical care group and 503 (50%) to the usual care group (Figure 1). A total of 117 patients were excluded because no pharmacy dispensing data were available for these subjects,

due to mismatch between data from the electronic records and the handwritten study entry forms. Thus, 899 patients (439 in the pharmaceutical care group and 460 in the usual care group) were eligible for analysis. Of the patients in the pharmaceutical care group, 62 (14%) did not attend any follow-up counseling session, whereas 29 (7%), 43 (10%), and 305 (69%) patients attended 3, 4, and all 5 counseling sessions, respectively.

Baseline characteristics of the patients are shown in Table 1. Mean age of all participants was 60.1 ± 11.1 years and 49% were male. Most patient characteristics were similar between the groups. However, significantly more patients in the usual care group had a history of CVD, and those in the usual care group classified their health status more often as moderate/poor. Significantly more patients in the pharmaceutical care group were prescribed atorvastatin, whereas fewer pharmaceutical care patients were prescribed rosuvastatin. A substantial number of patients (52%) started statin therapy at a medium equipotency score, equivalent to a simvastatin dose of 20 mg/day or an atorvastatin dose of 10 mg/day.

DISCONTINUATION OF STATIN TREATMENT

Figure 2 presents the Kaplan-Meier curve, comparing discontinuation of statin therapy over time between patients in the pharmaceutical care and usual care groups. Of the 899 patients, 58 were censored (20 in the pharmaceutical care group and 38 in the usual care group) because they died or left the study pharmacy before the end of follow-up. A total of 47 (11%) patients in the pharmaceutical care group and 72 (16%) patients in the usual care group discontinued statins within 6 months after the initiation of treatment (p value for log-rank test = 0.026). The corresponding percentages at 1 year after the start of therapy were 23% and 26%, respectively, in the pharmaceutical care and usual care groups (p value for log-rank test = 0.21). The hazard rate ratio of discontinuing statin therapy, as determined by the Cox proportional hazard analysis, showed that patients in the pharmaceutical care group had a statistically significantly lower rate of discontinuation within 6 months after initiating therapy than did patients in the usual care group (HR 0.66, 95% CI 0.46 to 0.96). Thus, patients in the pharmaceutical care group were 34% less likely to discontinue treatment, or 1.52 (95% CI 1.04 to 2.17) times more likely to persist with treatment compared to patients in the usual care group. Twelve months after therapy was initiated, this difference in discontinuation rate was not statistically significant (HR 0.84, 95% CI 0.65 to 1.10).

Analyses of discontinuation rates by subgroups are shown in Figure 3. We noted a significant treatment-by-subgroup interaction between patients using ≤5 or >5 medications at the ATC3-level (treatment-by-subgroup interaction, p = 0.028), which indicated that patients using more medications were less likely to benefit from the pharmaceutical care program. Although patients aged 50 years or younger, females, the higher educated, and patients who did not implement other lipid-lowering strategies seemed to gain more benefit from receiving pharmaceutical care, the differences in effect of the pharmaceutical care program between the subgroups were not statistically significant.

MEDICATION POSSESSION RATIO AND STATIN ADJUSTMENTS

The median MPR (25th-75th percentile) was 99.5% (96.9-100%) in the pharmaceutical care group and 99.2% (95.6-100%) in the usual care group (p = 0.14). Only 37 patients (8%) in the pharmaceutical care group and 54 patients (12%) in the usual care group had an MPR <90% (χ^2; p = 0.10). There was no significant difference between the groups in the percentage of patients switching to a statin with a different equipotency score.

LIPID LEVELS

In patients receiving pharmaceutical care, both mean total cholesterol and LDL-C levels declined significantly

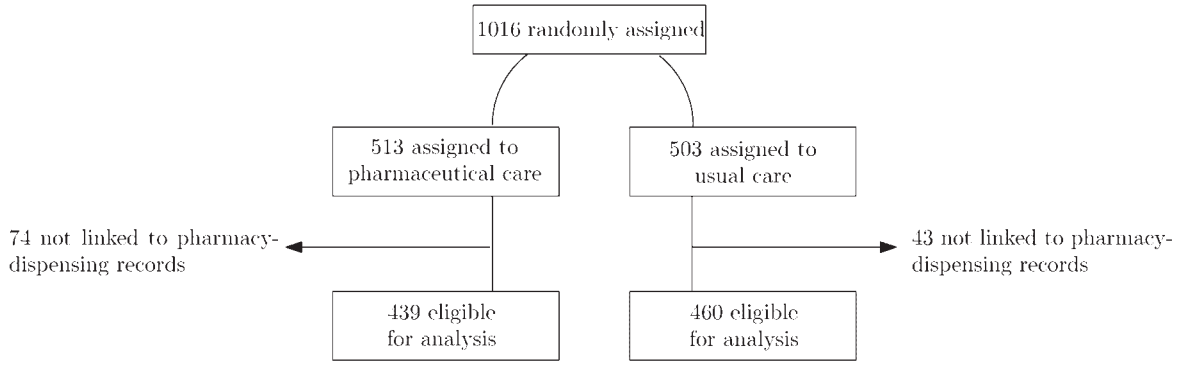

Figure 1. Patient enrollment.

during the study. The average reduction in total cholesterol and LDL-C was 17.2 mg/dL (95% CI 12.3 to 22.0) and 9.47 mg/dL (95% CI 5.02 to 13.9), respectively. Three months after initiating statin therapy, 65% of these subjects reached the target LDL-C level of below 115 mg/dL. At 6 and 12 months after treatment, these percentages were 72% and 77%, respectively. A higher percentage of adherent patients (MPR ≥90%) than nonadherent patients reached target LDL-C levels after 3 months (67% vs 45%, respectively; p = 0.01) and 6 months (74% vs 50%, respectively; p = 0.01). Spearman's correlation showed a significant negative association between the MPR and total cholesterol (r = –0.16; p = 0.002) and a trend toward a negative association between the MPR and LDL-C level (r = –0.10; p = 0.08).

Table 1. Baseline Patient Characteristics in the Pharmaceutical Care and Usual Care Groups

Characteristic	Pharmaceutical Care[a]	Usual Care[b]
Age, y (mean ± SD)	60.2 ± 10.9	60.1 ± 11.3
Male, n (%)	207 (47)	230 (50)
Dutch origin, n (%)[c]	359 (91)	380 (93)
Marital status, n (%)[c]		
married/living together	297 (80)	325 (83)
unmarried/widowed/divorced	74 (20)	67 (17)
Level of education, n (%)[c,d]		
low	156 (42)	162 (42)
intermediate	160 (43)	158 (40)
high	53 (14)	70 (18)
Comorbidities, n (%)[c]		
hypertension	169 (43)	200 (49)
diabetes mellitus	115 (29)	111 (27)
respiratory disease	30 (8)	35 (9)
History of CVD, n (%)[c,e]	117 (30)	146 (37)
Family history of hypercholesterolemia, n (%)[c]	96 (24)	112 (27)
Lifestyle factors, n (%)[c]		
current smoker	93 (24)	88 (22)
alcohol use ≥1 time/wk	73 (20)	68 (17)
following a specific diet	155 (40)	160 (40)
Other lipid-lowering strategies, n (%)[c]		
smoking cessation or reduction	53 (14)	42 (10)
reducing alcohol consumption	52 (13)	50 (12)
eating healthier	184 (47)	199 (49)
becoming more physically active	148 (38)	169 (42)
using plant sterol/stanols	154 (39)	166 (41)
Self-perceived health, n (%)[c,e]		
(very) good	276 (74)	273 (69)
moderate/poor	96 (26)	125 (31)
Statin, n (%)[d]		
simvastatin	157 (36)	153 (33)
pravastatin	40 (9)	59 (13)
atorvastatin[e]	169 (39)	139 (30)
rosuvastatin[e]	68 (15)	98 (21)
fluvastatin	4 (1)	11 (2)

CVD = cardiovascular disease.
[a]N = 439.
[b]N = 460.
[c]Numbers vary due to missing responses in the questionnaire. Percentages are calculated without missing values.
[d]Due to rounding, percentages may not total 100%.
[e]Statistically significant difference, p < 0.05, χ^2 test.

Discussion

Patients who understand the benefits of treatment and are satisfied with health-care provider communication, and those with frequent follow-up lipid tests, have been shown to be more adherent to statin therapy.[30] In our study, a community pharmacy–based pharmaceutical care program composed of patient counseling and feedback on achieved lipid levels was associated with modestly lower discontinuation rates of statin therapy. Compared to patients in the usual care group, those in the pharmaceutical care group were 34% less likely to discontinue treatment within 6 months (p = 0.03) and 16% less likely to discontinue treatment within 1 year after initiating statin therapy (p = NS). This difference in effect on discontinuation rates between 6 and 12 months might imply that frequent counseling sessions (every 3 months) are necessary to maintain the positive effects. However, the fact that the difference between groups in discontinuation rates at 12 months did not reach statistical significance could also be explained by other factors. Most importantly, discontinuation rates in the usual care group were lower than anticipated. The margin for improvement was therefore less than that hypothesized in the power calculation. This might be due to the fact that adherent patients and pharmacies that had already been involved in advanced provision of pharmaceutical care were more willing to participate in the program. Moreover, adherence to therapy in the usual care group might have been enhanced because the subjects were aware that their behavior was being monitored. Several studies aimed at improving adherence have shown unexpected high adherence in usual care groups.[31,32] The fact that patients included in the study reported a relatively high proportion of health-promoting behavior modifications suggests that study patients were more aware of their lipid levels and cardiovascular risk. Therefore, the effect of this pharmaceutical care program on adherence might be higher in routine medical practice.

Another reason for the lack of effect of the pharmaceutical care program on 1-year discontinuation rates is that 19% and 31% of the patients randomized to the pharmaceutical care group did not attend the follow-up counseling session at 6 and 12 months, respectively. Patients not adhering to the study protocol cannot benefit optimally from the program, leading to a diluted treatment effect. When this program is being implemented in daily medical practice,

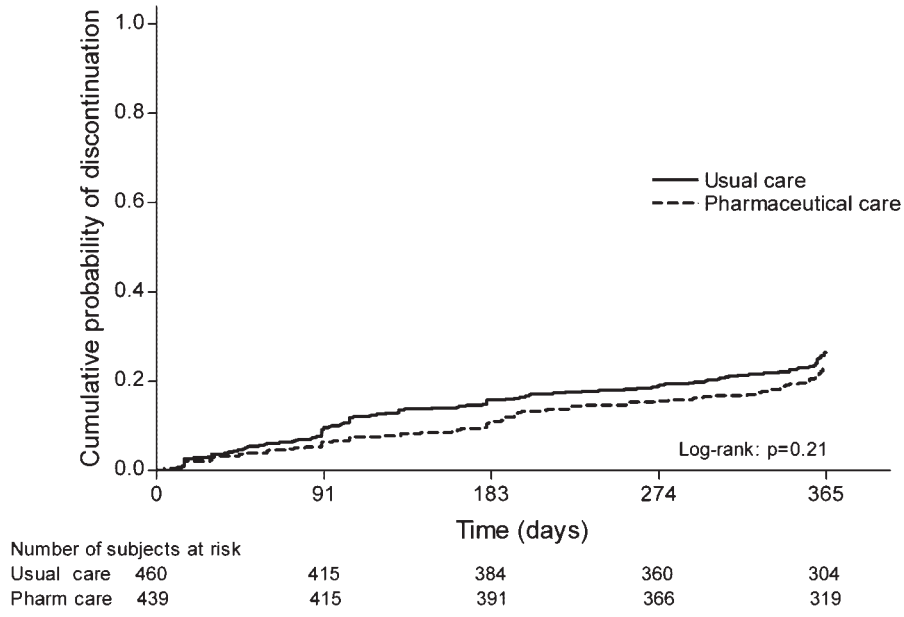

Figure 2. Kaplan-Meier curve for discontinuation of statin agents in patients in the pharmaceutical care group and in the usual care group (n = 899).

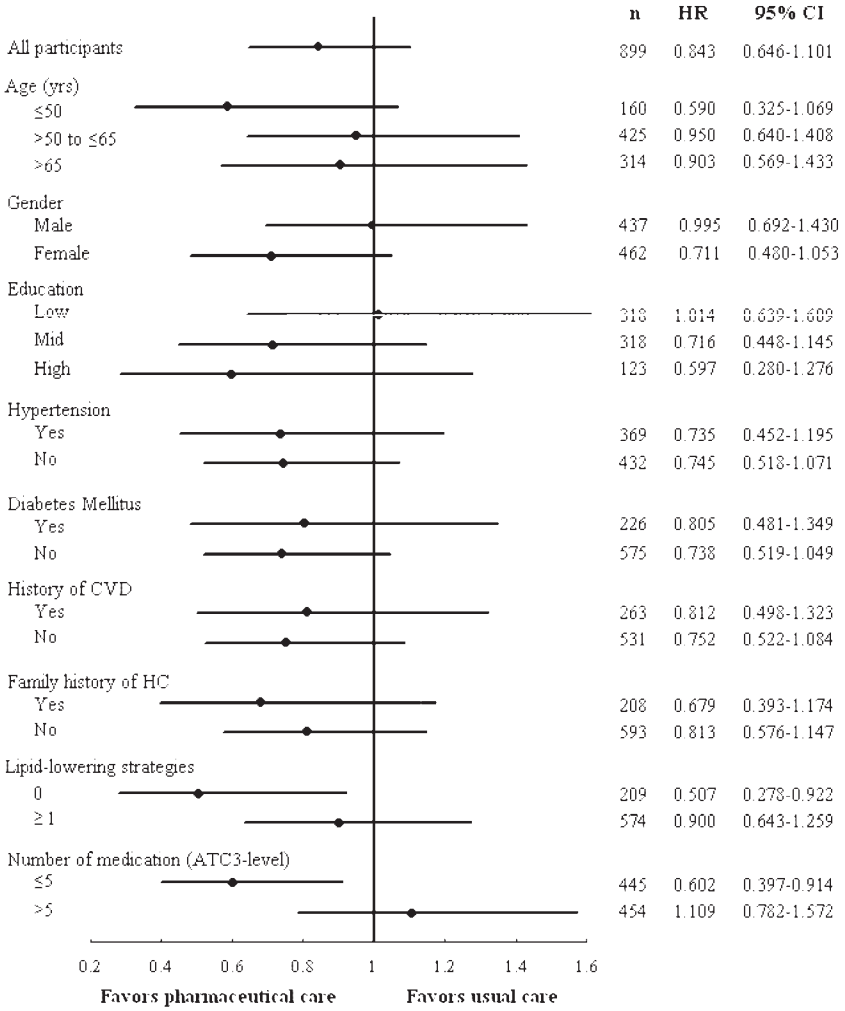

Figure 3. Incidence of discontinuation of statin agents in subgroups of the STatin Intervention research ProjecT according to Cox proportional hazard analyses. ATC3-level = Anatomical Therapeutic Chemical classification level 3; CVD = cardiovascular disease; HC = hypercholesterolemia.

an effort should be made (eg, by sending reminders and contacting patients who did not show up for their scheduled counseling session) to ensure that patients adhere to the counseling sessions. In our study, we present only results obtained from an intention-to-treat analysis. Analyzing results according to the per protocol principle of including only patients who had at least 1 follow-up counseling visit could introduce selection bias[33] due to associations between discontinuation of statin therapy and study dropout.

Finally, significantly more patients in the usual care group reported a history of CVD. This might have affected our results, as it is known that persistence with statin therapy is better among patients with preexisting CVD.[34] However, including CVD status as a confounder in Cox proportional hazard analysis did not change our results.

Although not statistically significant, the pharmaceutical care program seemed to be more effective in younger patients, females, the higher educated, and patients not taking many other medications (ie, patients generally classified as having a lower cardiovascular risk profile). Several observational studies have shown lower statin adherence among these patients.[35-38] Therefore, the margin of improvement might be greater in these subgroups.

Despite the high MPR, we found significant associations between differences in the MPR and total cholesterol– and LDL-C–lowering effects. Because lipid levels were measured only in the pharmaceutical care group, we were not able to study the effects of the pharmaceutical care intervention on lipid levels. Measuring lipid values in the usual care group probably would have influenced patients' behavior and thereby would have increased adherence in the usual care group. As a result, the effect of the intervention would have been diluted. However, as discussed earlier, it is still conceivable that adherence to therapy is higher in the usual care group compared to daily medical practice.

We did not observe more patients switching to another type or dose of statin in the pharmaceutical care group. Apparently, measuring lipid levels can be seen primarily as a method to give feedback to patients on the effect of statin treatment and does not result in adjustments of drug therapy. However, a lack of feedback from the pharmacist to the physician might also be a reason for the absence of dosage or drug adjustments.

In our study we used pharmacy dispensing data to calculate patient adherence to statin medication. These data present many advantages over self-reported adherence and medical records. Dispensing data are not suspect to patient-related recall bias and reduce nonresponse bias. However, uncertainty still exists as to whether dispensed drugs are actually being taken according to the prescribed regimen. In a study monitoring patient adherence to lipid-lowering therapy in clinical practice, it was found that, during the monitoring period of 6 months, approximately 60% of patients erroneously took multiple doses of statins per day.[39] In addition, we did not have information for many patients about the reason for discontinuation, and therefore we were unable to assess whether statin therapy was discontinued for clinical reasons. However, this would seem uncommon, as statin therapy is mostly indicated over a patient's lifetime and statins have a relatively mild adverse event profile.[40] Another limitation of our study is that we could not perform a double-blind study because of the nature of the intervention studied in this trial.

We recognize that randomization at the patient level, rather than at the pharmacy level, may have contaminated the care received by the patients in the usual care group by pharmacists' knowledge of the pharmaceutical care program. This would have increased the risk of a type II error (ie, incorrectly accepting the null hypothesis) and therefore could have diluted the effect size. In our study, however, extra time was scheduled for patients in the pharmaceutical care group for measuring the lipid levels and for counseling. Patients randomized to the usual care group visited the pharmacy only to refill their statin prescription. The alternative of a cluster-randomized trial would have given rise to other problems, such as recruitment bias, since participants are recruited after the clusters have been randomized.[41-43]

In conclusion, we demonstrated the feasibility and effectiveness of a community pharmacy–based pharmaceutical care program to improve medication adherence in new users of statins. Although improvements in adherence were modest, the program is convenient for the patients because counseling sessions are linked to the prescription refill dates. Moreover, the interventions are relatively inexpensive and easy to implement; the lipid tests cost about $80 per patient and counseling sessions take an additional hour per patient. Therefore, the program can be applied easily to a larger population and have a large impact on population level. Health economic studies should be performed to fully assess the cost-effectiveness of this pharmaceutical care program.

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Conflict of interest: Authors reported none

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Programa de Cuidado Farmacéutico Para Mejorar la Adherencia a la Terapia de Estatina: Estudio Aleatorio Controlado

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EXTRACTO

TRASFONDO: A pesar de los efectos beneficiosos conocidos de las estatinas, muchos pacientes no se adhieren a los regímenes de medicación crónica.

OBJETIVO: Implementar y evaluar la eficacia de un programa de cuidado farmacéutico en la farmacia de comunidad desarrollado para mejorar la adherencia del paciente a la terapia con estatinas.

METODOLOGÍA: Estudio abierto, prospectivo, aleatorizado, y controlado se realizó en 26 farmacias de comunidad en los Países Bajos. Los nuevos pacientes de las estatinas con 18 años o más fueron asignados aleatoriamente para recibir la atención habitual o una intervención farmacéutica. La intervención consistió en 5 sesiones de consejería individual por un farmacéutico durante un período de 1 año. Durante estas sesiones, los pacientes recibieron educación estructurada sobre la importancia de la adherencia a los medicamentos. Los niveles de lípidos fueron medidos y la asociación entre los niveles de adherencia y los niveles de lípidos fueron discutido. La adherencia a la terapia con estatinas se evaluó con las tasas de descontinuación en 6 y 12 meses después del inicio de las estatinas y la relación de posesión de medicamentos (MPR).

RESULTADOS: Un total de 899 sujetos (439 en el grupo de cuidado farmacéutico y 460 en el grupo de cuidado habitual) fueron evaluados para el análisis de la eficacia. El programa de cuidado farmacéutico resultó en una una tasa significativamente menor en la descontinuación dentro de los 6 meses después de iniciar el tratamiento (HR 0.66, CI 95% 0.46-0.96). No hubo diferencia significativa entre los grupos en la descontinuación en los 12 meses (HR 0.84, CI 95% 0.65-1.10). MPR fue muy alto (>99%) en ambos grupos y no hubo diferencia entre los grupos.

CONCLUSIONES: Se demostró la viabilidad y eficacia de un programa de cuidado farmacéutico en la farmacia de comunidad para mejorar la adherencia a los medicamentos en los nuevos usuarios de estatinas. Sesiones de consejería frecuentes (cada 3 meses) son necesarios para mantener los efectos positivos de la descontinuación. Aunque las mejorías son modesta, el programa puede ser fácilmente aplicado a una población más grande y tener un gran impacto; y las intervenciones son relativamente pocos costosas y fáciles de implementar en la práctica clínica.

Traducido por Wilma M. Guzmán-Santos

Une Programme de soins Pharmaceutiques pour Améliorer l'Adhésion des Patients à la Prise des Statines: Une Étude Randomisée Contrôlée

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RÉSUMÉ

OBJECTIF: Mettre en place et évaluer l'efficacité d'un programme de soins pharmaceutiques en officine pour améliorer l'adhésion des patients à la prise des statines.

MÉTHODES: Une étude ouverte, prospective, randomisée a été effectuée dans 26 officines aux Pays-Bas. Les nouveaux utilisateurs de statines âgées de plus de 18 ans ont été répartis au hasard pour recevoir des soins usuels ou l'intervention d'un pharmacien. Les interventions consistaient en 5 sessions individuelles de conseils aux patients effectuées par le pharmacien durant une période d'une année. Au cours de ces sessions, les patients ont reçu de l'information structurée concernant l'importance de prendre ses médicaments, les cibles visées de cholestérol et l'association entre l'adhésion et les niveaux de cholestérol. L'adhésion à la prise des statines a été mesurée selon le taux d'arrêt à 6 et 12 mois suite à la phase d'initiation de la statine et le ratio de possession de médicaments.

RÉSULTATS: Un nombre de 899 patients (439 dans le groupe soins pharmaceutiques et 460 dans le groupe soins usuels) a été évalué. Le programme de soins pharmaceutiques a eu un taux d'arrêt significativement plus bas en dedans de 6 mois du début du traitement (HR 0.66; 95% CI 0.46-0.96). Aucune différence significative entre les 2 groupes n'a été observée dans l'arrêt du traitement à 12 mois (HR 0.84; 95% CI 0.65-1.10). Le ratio de possession de médicament était très élevé (>99%) dans les 2 groupes soit pour le groupe de soins pharmaceutiques et pour le groupe de soins usuels et il n'y avait pas de différence entre les 2 groupes.

CONCLUSIONS: Les auteurs ont démontré la faisabilité et l'efficacité d'un programme de soins pharmaceutiques pour améliorer l'adhésion chez des nouveaux utilisateurs de statines. Des sessions d'information régulières (aux 3 mois) sont nécessaires pour maintenir les effets positifs. Même si les améliorations sont modestes, le programme peut être facilement mis en place et avoir des impacts importants puisque les interventions ne sont pas dispendieuses et facilement mises en place.

Traduit par Louise Mallet